SAMSUNG ELECTRONICS Co., Ltd.

510(k) Premarket Notification - Traditional

MAY 2 8 2014

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted accordance with requirements of 21 CFR 807.92

1. **Date:** February 7, 2014
2. **Submitter**
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3. **Primary Contact Person**
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4. **Secondary Contact Person**
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5. **Device**
   A. Trade Name: XGEO GC80
   B. Common Name: Digital Diagnostic X-ray System
   C. Classification Name: System, X-ray, Stationary
   D. Product Code: KPR

6. **Predicate Device**
   A. Manufacturer: SAMSUNG ELECTRONICS Co., Ltd.
   B. Trade Name: XGEO GC80
   C. 510(k) Number: K123098

D. 510(k) Decision Date: January 18, 2013

7. Device Description

The XGEO GC80 digital X-ray imaging system is to be used to take and store image for diagnosis of patients. It consists of the High voltage generator (HVG), Ceiling suspension, Detector, X-ray tube, Patient table, Wall stand, Collimator and etc.

8. Intended Use

The XGEO GC80 Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.

9. Comparison with predicate device :

Samsung Electronics Co., Ltd., believes that the XGEO GC80 is substantially equivalent to our current product, the XGEO GC80 (K123098).

The proposed XGEO GC80 includes detectors (SDX-4336CP, SDX-4343CS) that were cleared in XGEO GC80 (K123098,) and adds new two detectors (S4335-W, S4343-W). These detectors are compared with those of the XGEO GC80 (K123098) of Samsung Electronics Co., Ltd. Through the comparison, it is proved that both devices are same or similar in many ways, but differences in two items were found. Specifically, differences in resolution, pixel pitch, and communication of detectors exist, but they are considered to have minor impacts on the safety and performance.

1) Resolution and pixel pitch: Pixel pitch, which is a measurement that indicates the distance between pixels and determines an image resolution, is different. It affects the image quality but has not an effect on safety.
2) Communication: The proposed device can interface with an external device through the wired and wireless communication methods, while Predicate Device supports only the wired one. This difference has no effect on safety.

The above differences do not have an effect on safety and effectiveness compared with the predicate device, XGEO GC80 (K123098).

In summary, the XGEO GC80 does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

In conclusion, the XGEO GC80 is substantially equivalent to XGEO GC80 (K123098).

10. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001). All test results were satisfactory.

11. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Samsung Electronics Co., Ltd. concludes that The XGEO GC80 is safe and effective and substantially equivalent to predicate devices as described herein.

12. Samsung Electronics Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 28, 2014

SAMSUNG ELECTRONICS Co., Ltd.
% Chulsin Kim
Regulatory Affairs Manager
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do, 443-742
REPUBLIC OF KOREA

Re: K140334
Trade/Device Name: XGEO GC80
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: April 25, 2014
Received: April 28, 2014

Dear Chulsin Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K140334

Device Name: XGEO GC80

Indications for Use:

The XGEO GC80 Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.

Prescription Use___X____ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K140334_____